

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Tomi JÄRVINEN et al.

Serial Number: 10/521,761

Group Art Unit: 1623

Filed: January 21, 2005

Examiner: Goon, Scarlett Y.

For: LIGNAN COMPLEXES

REQUEST FOR RECONSIDERATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

March 30, 2009

Sir:

In response to the Official Action mailed December 30, 2008, please reconsider this application in view of the following remarks. Claims 13-21 are pending.

The 35 U.S.C. § 102(e) rejection of claims 13, 17 and 21 over U.S. Patent Publication US 2005/0169947 to Korte et al. is respectfully traversed. Applicants have previously made a priority claim of August 29, 2002 based on Finnish patent application 20021545. See their Declaration for U.S. Patent Application. Their priority claim has been perfected, as a certified copy of the Finnish patent application in English has been received by the U.S. Patent Office (Official Action, page 2).

The effective reference date of Korte et al. is its May 15, 2003 PCT filing date. 35 U.S.C. § 102(e). See also MPEP §

2136.03. Accordingly, Korte et al. is not a reference against the claims of this application. Reconsideration and withdrawal of the anticipation rejection of claims 13, 17 and 21 are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 14-16 and 18-20 over Korte et al. in view of U.S. Patent No. 6,559,168 to Marfat et al. and U.S. Patent No. 6,395,279 to Empie et al. is traversed. The claimed inclusion complex comprises hydroxymatairesinol, its isomer or its ester (hereinafter collectively referred to as HMR), and a cyclodextrin.

As discussed above, Korte et al. is not a reference against the claims of this application. Marfat et al. and Empie et al. both fail to disclose or suggest the claimed inclusion complex. Reconsideration and withdrawal of the obviousness rejection of claims 14-16 and 18-20 over Korte et al. in view of Marfat et al. and Empie et al. are respectfully requested.

The 35 U.S.C. § 103(a) rejection of claims 13-21 over U.S. Patent 6,451,849 to Ahotupa et al. in view of U.S. Patent No. 6,559,168 to Marfat et al. is respectfully traversed. The claimed inclusion complex comprises HMR and a cyclodextrin. The inventors have discovered the claimed complex exhibits improved dissolution

of HMR into aqueous solution, and provides improved stability. Moreover, encapsulation of HMR into the cyclodextrin molecule masks the slightly bitter taste of HMR (Specification, page 5, lines 11-16).

The cited combination of references fails to raise a prima facie case of obviousness against the claimed composition because these references, taken together, do not disclose or suggest an inclusion complex of HMR and a cyclodextrin, and because one of ordinary skill in the art would not have a reasonable expectation of success regarding formation of a cyclodextrin inclusion complex of HMR.

The Patent Office concedes Ahotupa et al. fails to disclose an inclusion complex of HMR (Official Action, page 9, lines 3-4).

Marfat et al. also fails to fairly suggest a cyclodextrin inclusion complex of HMR. Instead, Marfat et al. makes only a brief reference to lignans as a class of PD4E inhibitors and cites two compounds (T-440 and T-2585) which are structurally dissimilar from HMR (for example, both compounds have fused rings, whereas HMR does not). See Col. 17, lines 30-49.

Marfat et al. does not disclose or suggest complexing lignans into cyclodextrins. Instead, Marfat et al. discloses a laundry

list of possible additives for its composition, including antimicrobial agents, antioxidants, buffering agents, chelating agents, dermatologically active agents, dispersing and suspending agents, emollients, emulsifying agents, excipients, sequestering agents such as cyclodextrins, solvents, and stabilizers. See Col. 258, line 16 to Col. 262, line 18. It is respectfully submitted the Patent Office has employed hindsight analysis to supply the motivation/suggestion absent from this lengthy (308 column) reference to form a cyclodextrin inclusion complex of HMR.

The field of cyclodextrin inclusion complexes is considered unpredictable, such that one of ordinary skill in the art would not have a reasonable expectation of success that HMR would form an inclusion complex with a cyclodextrin. Thus, although the complexation of small molecule organic compounds into cyclodextrins is generally known, the reality is that it is very hard for any scientist in the field to predict whether a compound will form an inclusion complex with cyclodextrin. See Connors, "The Stability of Cyclodextrin Complexes in Solution," 97 Chem. Rev. 1325 (1997). Very small changes in compound structure can cause dramatic change in the ability of the compound to form sufficiently stable complexes which provide an advantage over non-cyclodextrin

containing formulations. Thus, much laboratory testing has to be carried out in order to determine whether a compound will successfully form a cyclodextrin inclusion complex.

In short, one of ordinary skill in the art would not be motivated by Ahotupa et al. and Marfat et al. to form a cyclodextrin inclusion complex with HMR, and would not have a reasonable expectation HMR would form an inclusion complex with a cyclodextrin. Reconsideration and withdrawal of the obviousness rejection of claims 13-21 over Ahotupa et al. in view of Marfat et al. are earnestly requested.

It is believed this application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 13-21, and issuance of a Notice of Allowance directed to those claims, are earnestly requested. The Examiner is urged to telephone the undersigned should she believe any further action is required for allowance.

It is not believed any fee is required for entry and consideration of this Amendment. Nevertheless, the Commissioner is

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authorized to charge Deposit Account No. 50-1258 in the amount of
any such required fee.

Respectfully submitted,

/James C. Lydon/

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Enclosure:

Connors, "The Stability of Cyclodextrin Complexes in
Solution," 97 Chem. Rev. 1325 (1997).